GUIDELINES

Management of Natural Rubber Latex Allergy

Selecting the Right Glove for the Right Task

in Health Care Facilities

Division of Epidemiology, Environmental and Occupational Health

Christine Todd Whitman
Governor

Christine Grant, J.D., M.B.A.
Commissioner

Dear Colleague:

The New Jersey Department of Health and Senior Services (DHSS) is issuing the enclosed *Guidelines* to assist health care facilities in the management of natural rubber latex allergy.

DHSS convened a Latex Allergy Task Force of stakeholders in New Jersey to provide advice and guidance on the many issues faced by latex-exposed individuals and the institutions in which they work. The members of the Task Force include representatives from health care, medical, and nursing associations; the glove manufacturing industry; an advocacy group; and academic institutions.

The Task Force has worked with the DHSS to develop these *Guidelines*. The language in the *Guidelines* is similar to that used in various educational publications, including a National Institute for Occupational Safety and Health document titled, "*Alert on Preventing Allergic Reactions to Natural Rubber Latex*," Occupational Safety Health Administration's Latex Allergy Technical Information Bulletin, and a position statement on latex allergy issued by the American College of Allergy, Asthma and Immunology. **The DHSS encourages health care facilities to implement the recommendations contained in the enclosed *Guidelines* and develop policies and procedures for the prevention and management of natural rubber latex allergy/sensitization that are specific and relevant to their own institution.**

The public health issues associated with the use of latex-containing products are of concern to all health care facilities to protect their employees and patients, and to reduce the potential for adverse reaction to latex-containing products without compromising critical infection-control procedures and practices.

The DHSS conducts surveillance of occupational diseases including work-related asthma attributable to latex exposure. Work-related asthma, including new onset and work-aggravated, is reportable under state regulations. Enclosed are the physician reporting regulations and a reporting form. Please feel free to copy the form and distribute it among your staff.

If you have any questions or comments, please call Barbara Gerwel, M.D., of the Occupational Health Service, at (609) 984-1863.

Sincerely,

Christine Grant
Commissioner

Enclosures
c: Barbara Gerwel, M.D.

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I. Introduction

Natural rubber latex (NRL) has proven effective in preventing transmission of many infectious diseases. Unfortunately, use of NRL gloves in this preventive effort has contributed to documented sensitization to NRL allergens of 1-6% of the general population, and 7-17 % of health care workers.[1,2] NRL exposure sources in the health care setting may induce sensitization or allergic reactions in health care workers and patients. Allergic reactions can include the more common mild rash and hay fever-like symptoms, as well as asthma, and, less commonly, life-threatening anaphylactic shock and death. The initial onset of allergic reactions can be delayed and may not cause symptoms for years.

To address health issues affecting employees exposed to NRL-containing products, the New Jersey Department of Health and Senior Services (DHSS) convened a Latex Allergy Task Force. The charge of the Latex Allergy Task Force was to provide guidance and advice to the DHSS regarding the prevention and management of NRL sensitization and allergy. Based on the National Institute for Occupational Safety and Health (NIOSH) Alert in 1997,[1] the Occupational Safety and Health Administration (OSHA) Technical Information Bulletin in 1999,[2] the Food and Drug Administration (FDA) rules and regulations in 1997,[3] and the FDA proposed rules in 1999,[4] the Task Force helped to develop this document which provides guidelines for the management of individuals who are working with or exposed to NRL products in the health care facility environment. Each health care facility should develop policies and procedures for the prevention and management of NRL allergy/sensitization that are specific and relevant to its own institution.

Both the federal Occupational Safety and Health Act and the New Jersey Public Employees Occupational Safety and Health Act require private and public employers, respectively, to provide employment free from recognized hazards which are known to cause injury, physical harm, or death.

The Americans With Disabilities Act provides guidelines for hiring and placing employees with disabilities. Employers must make a “reasonable accommodation” to allow disabled individuals to perform the essential functions of a job.

II. Background Information

A. Natural Rubber Latex

NRL products are manufactured from a milky fluid derived from the rubber tree, *Hevea brasiliensis*. NRL is comprised of 30-40% rubber (*cis*-1,4 polyisoprene), 2% resin, 60-65% water and 2-5% lipid and protein. At least eight NRL proteins are known to be potent allergens that can induce IgE antibodies production in NRL-exposed individuals. Chemicals added to the milky fluid during the processing and manufacture of NRL include accelerators (thiurams, carbamates) and anti-oxidants (phenylenediamine), which may cause a delayed hypersensitivity reaction (allergic contact dermatitis). NRL proteins are present in many different products such as personal protective equipment (especially surgeon’s and patient examination gloves), emergency equipment, hospital supplies, household objects, and office supplies.

B. Problems Associated with Natural Rubber Latex Glove Use and Other Natural Rubber Latex-Containing Medical Products

Employees in the health care industry are at risk for developing NRL sensitization, NRL allergy and/or chemical allergy because they frequently use NRL gloves and other NRL-containing medical products.

Three types of adverse health reactions to gloves and medical products that contain NRL can occur:

- ***Irritant Contact Dermatitis***: A non-allergic skin rash characterized by hand erythema, pruritus, dryness, and cracking. This reaction is caused by skin irritation from using gloves and possibly by contact exposure to other workplace products and chemicals.

- ***Allergic Contact Dermatitis (delayed-type hypersensitivity)***: A specific immune response to the chemical additives, such as accelerators or antioxidants (thiurams, carbamates, phenylenediamine) added to NRL during harvesting, processing, or manufacturing of NRL products. Acute dermal reactions include erythema and vesicle formation (similar to the skin eruption after poison ivy exposure). The lesions typically appear 24-96 hours after exposure. Subsequently, chronic exposure may cause the skin to become dry, crusted and thickened.

- ***NRL Allergy (immediate-type hypersensitivity)***: Certain NRL proteins may cause the induction of IgE antibodies. Reactions usually begin within minutes of exposure of a sensitized individual to NRL allergens, but they can occur hours later. Mild allergic reactions to NRL involve skin redness, hives, or itching. More severe reactions may involve respiratory symptoms such as runny nose, sneezing, itchy eyes, scratchy throat, bronchospasm, asthma, gastrointestinal upset, abdominal pain and diarrhea. Anaphylaxis and death have occurred following NRL exposure.

The primary risk factor in producing sensitization or inducing allergic reaction is exposure to certain NRL proteins. The amount of NRL protein exposure necessary to sensitize an individual is unknown. Reductions in exposure to NRL proteins have been reported to be associated with decreased risk of sensitization and allergic symptoms.[1,2,4,5] NRL proteins responsible for sensitization and or allergic reactions have been shown to attach or adsorb to cornstarch that is used in powdered NRL gloves to facilitate donning.[1,2,4] When the gloves are changed, NRL protein/powder particles are aerosolized and may be inhaled or may contact mucous membranes. Frequent contact with NRL products increases the risk for sensitization and developing NRL allergies. While NRL exposure is the primary factor for developing NRL sensitization and allergy, certain populations are more susceptible to develop sensitization or NRL allergies based on pre-existing conditions, including atopy, allergies to certain foods (avocado, banana, tomato, chestnuts, kiwi fruit, papaya, etc), hand dermatitis, frequent or long term urinary catheterization, and multiple surgical procedures.

III. Management of Natural Rubber Latex Allergy in Health Care Facilities

A. Management Commitment

The employer is responsible for managing safety and health at the workplace. Management must provide a safe and healthy environment for employees and patients.

B. Latex Allergy Task Force

A multidisciplinary Latex Allergy Task Force should be established in all health care facilities. This task force should consist of individuals from a variety of settings within the health care facility, such as: occupational health, infection control, pharmacy, material purchasing services, risk management, pediatrics, operating rooms, specialty units, critical care units, home health, emergency medicine services, human resources, patient services, administration, laboratory, housekeeping and maintenance, nutrition, surgery, allergy, and clinics or outpatient services. It would be beneficial to provide opportunities for comments from NRL sensitive or NRL allergic individuals. The Task Force should provide continuous input, education, and updated information, and make recommendations for all policies and procedures

necessary for appropriate management and prevention of NRL sensitization and allergy in the health care facility.

C. Natural Rubber Latex-Safe Environment

To minimize exposure to airborne NRL proteins in a health care facility, lower powder or lower protein and lower allergen NRL gloves, or non-NRL gloves [4,6] should be used throughout the facility. Purchasers and users should contact the manufacturer for further information regarding powder, protein or allergen level in particular gloves, because the powder, allergen and protein content of NRL gloves varies widely.[4,6] Selecting non-powdered NRL gloves offers the additional benefit of reducing the risk of sensitization and possible systemic allergic responses among sensitized individuals.[1,2,4,5] Non-NRL gloves should be used for activities that do not involve contact with infectious materials, e.g., food preparation, routine housekeeping, general maintenance. NRL toy balloons should not be permitted in the health care facility. Routine maintenance and cleaning of the facility's heating, ventilation, and air conditioning system should be performed to reduce NRL protein contamination and improve the general indoor air quality.

The health care facility's goal should be to provide a NRL-safe environment for *patients and employees diagnosed with NRL allergy*. NRL-safe areas are those reasonably free from airborne NRL proteins.

D. Employee-Related Issues

The employer should assume the responsibility for the prevention and management of work-related NRL allergy among health care facility employees.

- ❑ During pre-placement exams, employees should be asked about any condition which might require accommodations;
- ❑ Employees should be educated upon employment and periodically thereafter regarding NRL allergy issues. Employees should be able to recognize the signs and symptoms of NRL allergy and other NRL-related illnesses and understand how exposures can be reduced;
- ❑ Employees who experience any signs or symptoms after exposure to NRL should report them promptly to the supervisor and the employee health service;
- ❑ The employer should develop a procedure for evaluation of employees with NRL allergy-related health problems. The evaluation should include a thorough medical and occupational history, including risk factors associated with NRL allergies; an appropriate physical exam, and indicated diagnostic testing and follow-up;
- ❑ Affected employees should be provided with product, disease, and treatment and prevention information;
- ❑ All reasonable efforts should be made to provide a NRL-safe environment. Health care workers diagnosed with NRL sensitivity or NRL allergy must wear non-NRL gloves. They should wear appropriate barriers when in contact with NRL products. They also should be provided with information on how to obtain a health alert bracelet to indicate their allergy as well as comprehensive instructions regarding emergency situations and reporting.

E. Patient-Related Issues

Patients diagnosed with NRL allergy should not have contact with NRL products including gloves, tubing, catheters, blood pressure cuffs, drains, masks, tourniquets, tape, and any other NRL-containing materials.

- ❑ All patients should be screened upon admission for any inpatient or outpatient procedure to determine a known or potential risk of developing a NRL allergic reaction;
- ❑ Patients with suspected NRL allergy should be referred to an allergist to determine specific sensitivities to NRL additives or NRL proteins and to indicate follow up procedures;
- ❑ A patient Natural Rubber Latex Allergy Care Protocol should be developed and implemented for patients with known or suspected NRL allergy, and staff should be re-educated periodically to assure awareness of the protocol;
- ❑ Patients with a confirmed NRL allergy diagnosis should be provided with appropriate education upon discharge. Topics may include avoidance of NRL, food interactions, product information and alternatives. Patients also should be provided with comprehensive instructions regarding emergency situations and with information on how to obtain a health alert bracelet to indicate their allergy. Information regarding their NRL allergy should be entered into their medical record;
- ❑ Designated NRL-safe areas of the emergency department, operating rooms, recovery rooms, intensive care units, radiology suites, dental suites, and other treatment areas should be available to NRL allergic patients. NRL-safe areas should be free of NRL glove powder, whether ambient or on surfaces, clothing or equipment;
- ❑ NRL allergic patients should be admitted only to NRL-safe rooms and other areas clearly designated as NRL-safe in which no NRL products are used;
- ❑ A "Natural Rubber Latex Precaution" sign should be posted at the door to NRL-safe rooms, at the bed/crib sides, on stretchers and wheelchairs of NRL allergic patients, and on the front of their charts;
- ❑ An emergency cart labeled "Latex free" with only NRL-free medical products should be available to hospital units/departments, in emergency departments, and in ambulances.

F. Evaluation of Gloves

The DHSS Latex Allergy Task Force suggests that health care facilities reduce the use of NRL gloves where appropriate alternatives can be substituted. The Task Force recommends the following preventive actions:

- ❑ Use non-NRL gloves for activities that involve contact with non-infectious materials, e.g., food preparation, routine housekeeping, gardening, general maintenance;
- ❑ In cases where NRL gloves are selected, use reduced powder, or reduced protein or reduced allergen NRL gloves. Contact the manufacturer for further information regarding powder, protein or allergen level in particular gloves because the powder, allergen and protein content of NRL gloves varies widely.[4,6] Selection of non-powdered NRL gloves offers the additional benefit of potentially reducing the risk of sensitization and possible systemic allergic responses among sensitized individuals;[1,2,4,5]
- ❑ When wearing NRL gloves, avoid the use of oil-based creams or lotions;
- ❑ Wash hands with a mild soap and dry thoroughly after wearing gloves;
- ❑ Consider glove evaluation criteria such as barrier efficacy, durability, leakage and tensile strength, chemical resistance, and comfort in use when selecting gloves. (see the accompanying DHSS Guidelines "*Selecting the Right Glove for the Right Task in Health Care Facilities*")

IV. Education

Health care facilities should develop an education program on NRL issues for all employees.

Employees should be educated upon employment and periodically about health issues related to NRL exposure. The educational material should be reviewed and updated periodically.

Some suggested methods for the education of employees and patients include newsletters, brochures, videos, conference sessions, professional journals, flyers, medical and nursing grand rounds, in-service education during staff meetings, NRL allergy support groups, patient and family information packets, and continuing education programs.

V. Reporting Requirements

A. Federal Occupational Safety and Health Act and the New Jersey Public Employees Occupational Safety and Health Act

Both the federal Occupational Safety and Health Act (for private employers) and the New Jersey Public Employees Occupational Safety and Health Act (for public employers) require employers to record and report occupational injuries and illnesses. These regulations require employers to record and report cases of irritant contact dermatitis, allergic contact dermatitis, and any other illnesses caused or aggravated by occupational exposures on the OSHA 200 *Log and Summary of Occupational Injuries and Illnesses* and on an *Occupational Injuries and Illnesses Survey* form, upon receipt from federal OSHA or the New Jersey Department of Labor. All NRL-related adverse reactions associated with medical devices should be reported to FDA MedWatch.

B. New Jersey Department of Health and Senior Services Reporting Regulations

The DHSS conducts surveillance on all types of work-related asthma, including asthma attributable to NRL exposure. Physicians must report work-related asthma, including new onset and work-aggravated, by regulation (N.J.A.C. 8:57-3.2).

VI. References

1. NIOSH Alert - "*Preventing Allergic Reactions to Natural Rubber Latex in the Workplace*," US Department of Health and Human Services (NIOSH) Publication No.97-135, 1997;7.
2. Technical Information Bulletin: "*Potential for Allergy to Natural Rubber Latex Gloves and other Natural Rubber Product*," US Department of Labor, OSHA, 1999.
3. US Food and Drug Administration. Federal Register Notice. Final Rule: "Natural Rubber-Containing Medical Devices; User Labeling." 1997 Sept 30; 62(189):51021-51030.
4. US Food and Drug Administration. Federal Register Notice. Proposed Rule: "Surgeon's and Patient Examination Gloves: Reclassification and Medical Glove Guidance Manual Availability." 1999 July 30; 64(146):41710-41743.
5. Statement Concerning the Use of Powdered and Non-Powdered Natural Rubber Latex Gloves, July 1997, American College of Allergy, Asthma & Immunology.
6. Yunginger, J., Jones, R., Fransway, A., et al. (1994). Extractable Latex Allergens and Proteins in Disposable Medical Gloves and other Rubber Products. Journal of Allergy and Clinical Immunology, 93:836-842.

Selecting the Right Glove for the Right Task in Health Care Facilities

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1. Background

Appropriate barrier protection is necessary when in contact with infectious and hazardous materials. Natural rubber latex (NRL) is a glove material that has been used in health care facilities for successful barrier protection for many years. In response to documented NRL allergy and sensitization in patients and health care workers, measures have been recommended to reduce the risk of NRL allergy and sensitization and allergy to chemicals that have been added to NRL during processing and manufacture. Reactions to NRL gloves and other medical products may be localized or systemic and may include dermatitis, conjunctivitis, rhinitis, urticaria, asthma, angioedema, and, rarely, anaphylaxis and death. Primary prevention of NRL sensitization and allergy involves reducing exposure of all workers to NRL proteins.

The reason for wearing gloves is to provide barrier protection from infectious and hazardous materials. All glove materials must maintain adequate barrier protection for their intended use and be appropriate for the hazard.

Medical gloves (surgeons' and patient examination) are regulated by the FDA, and must meet the FDA criteria for marketing, manufacturing, and testing. Glove manufacturers must submit to FDA the results of a variety of tests to ensure high quality and effective performance of gloves. The FDA requires that all medical devices containing NRL be labeled with the following statement: "Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions." Gloves made from NRL or other materials and used for medical purposes should be labeled as medical gloves.

Based on regulations of the Food and Drug Administration (FDA) and recommendations of the Occupational Safety and Health Administration (OSHA) and the National Institute for Occupational Safety and Health (NIOSH), the New Jersey Department of Health and Senior Services (DHSS) Latex Allergy Task Force recommends the reduction of the use of NRL gloves where appropriate alternatives can be substituted. In cases where NRL gloves are selected (i.e., as per Universal Precautions), the Task Force recommends the use of lower powder*, lower protein* or lower allergen* NRL gloves. Selecting non-powdered NRL gloves offers the additional benefit of reducing the dissemination of NRL proteins into the environment and reducing sensitization, and possible systemic allergic responses among sensitized individuals.[1-3]

**Purchasers and users should contact the manufacturer for further information regarding powder, protein or allergen level as the powder, allergen and protein content of NRL gloves varies widely.*[4,5]

Standards and guidelines for glove manufacture come from several standard setting organizations: the American Society for Testing and Materials, the American National Standards Institute, the National Fire Protection Association, FDA and OSHA. Performance recommendations for glove materials include characteristics such as watertight integrity, sizing and dimensions, strength, elongation and modulus (the stress required to stretch rubber to a given elongation), bacteriophage penetration resistance, heat aging resistance, and isopropanol degradation resistance.

Unfortunately, no one glove is appropriate for every health care provider in every situation. The decision to use gloves, glove use and choices should complement institutional NRL allergy management protocols and guidelines on managing and preventing occupational health and hazardous exposure. This strategy may reduce costs and improve infection control practices in the health care facility through the education of personnel on appropriate glove choices. Numerous factors affect glove choice and use, and these are noted below.

2. Criteria for Glove Use

- ***In Use Issues***: Exposure to infectious organisms (viruses, bacteria); physical stress/durability (orthopedic, cardiovascular surgery); chemical resistance (disinfectants, drugs).

- ***User Preferences***: Sterility, comfort and fit (length, palm width, flexibility), texture (tactile sensations, slipping).

- ***Match Glove to User Criteria through In-Use Performance Evaluation***: Barrier efficacy, physical stress/durability, chemical resistance, comfort in use**,** length of usage.

3. Barrier Efficacy

Medical gloves must protect the skin from blood and other potentially infectious body fluids and materials. The FDA requires that medical gloves must pass a 1,000 milliliters watertight test, which detects small holes (20,000-30,000 nanometers). This test does not detect holes as small as the size of the Hepatitis B or Hepatitis C viruses or HIV. While the FDA does not currently require viral penetration testing for medical gloves, to insure high quality products, some manufactures perform the test voluntarily using the bacteriophage Phi X 174. The results of the test permit detection of holes in the 1,000-5,000 nanometers range and may be obtained from the manufacturer or supplier of the medical gloves. The laboratory viral penetration tests cannot assess in-use factors such as virulence, mode of transmission, mechanism of entry, skin barrier, and immunologic status, or the impact of glove hydration and physical activity.

4. Physical Stress/Durability

Durability is defined by how well a glove maintains its barrier protection when subjected to physical stress. Gloves must meet tests of tensile strength (the amount of stretching stress required to break the latex film) and ultimate elongation (the difference in length when latex has been stretched to its breaking point). Gloves must meet these requirements both before and after accelerated aging. Rather than focus on the material alone, the task that is to be performed may guide in the selection of the appropriate glove. A deciding factor is the length of time to complete a procedure (a short period of time with few manipulations, or an extended period of time with hard use). Splitting, tearing, or developing large holes are obvious signs of glove failure. However, small pinholes may develop which are not readily detectable.

5. Chemical Resistance

Gloves are exposed to chemicals including disinfectants, sterilizing and chemotherapeutic agents. Very often the manufacturer of the chemical product will suggest or discourage particular glove material. The glove manufacturer should be contacted for recommendations concerning specific compatibility and chemical resistance of their medical gloves in the health care environment.

6. Comfort in Use

Gloves must be available in a range of sizes, lengths and cuffs to fit all users. Loose or tight fitting gloves may make it difficult or impossible to perform a given task. Flexibility and elasticity should also be considered. Comfort is a subjective characteristic, but has greater importance the longer one is required to wear a glove. For some tasks, a textured glove may improve the grip, but decrease the sense of touch.

7. In Addition to the Above:

- Medical gloves, if marked sterile, must pass requirements for sterility testing specified in the latest edition of the U.S. Pharmacopeia.
- Lubricants to facilitate donning and removal of gloves must meet safety and efficacy standards established by the U.S. Pharmacopeia for Absorbable Dusting Powder, and must have pre-market approval of the FDA.
- There are allergenic proteins in NRL medical gloves, and potentially over 200 different processing chemicals. Gloves available to reduce allergen exposure can include "powder-free" NRL gloves[4] or synthetic non-NRL medical gloves. It is essential to characterize any allergic problems in health care staff through institutional latex management protocols. Those employees who become sensitized or allergic to NRL must wear non-NRL gloves.
- Isopropanol degradation resistance must be specified because isopropanol is commonly used in situations in which medical gloves are worn.
- The FDA is currently proposing that all medical gloves bear labeling that states the powder per glove and the upper limit recommended by FDA which is proposed to be no more than 120 milligrams per glove. The new regulation would also require that all medical gloves bear labeling that states the upper limit of water extractable protein per glove and the upper limit recommended by FDA which is no more than than 1,200 micrograms per glove.[4]
- The FDA also plans to propose that medical gloves be reclassified to Class II Medical Devices.[4]

8. References

1. US Food and Drug Administration. Federal Register Notice. Final Rule: "Natural Rubber-Containing Medical Devices; User Labeling." 1997 Sept 30; 62(189):51021-51030.
2. Technical Information Bulletin: "*Potential for Allergy to Natural Rubber Latex Gloves and other Natural Rubber Products*," US Department of Labor, OSHA, 1999.
3. NIOSH Alert -"*Preventing Allergic Reactions to Natural Rubber Latex in the Workplace*," US Department of Health and Human Services (NIOSH) Publication No.97-135, 1997;7.
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